REMARKS/ARGUMENTS

Status of the Claims.

Claims 1-30 are currently pending in this application with claims 1-22 being withdrawn from current consideration. To more clearly claim the current embodiment, claims 23, 24, 27, 28, and 29 are amended herein and claim 31 is newly added. The changes introduce no new matter and are fully supported by the application as filed. The current Office Action rejects claims 23-25, 26, and 28-30 as allegedly failing to comply with the written description requirement of 35 U.S.C. §112. Claims 23-30 are rejected as allegedly anticipated under 35 U.S.C. § 102(b) by Penichet, *et al.* (*J. Immunol.*, 1999, 163:4421-4426) as evidenced by Zerega, *et al.*, (*J. Cell Science*, 2001, 114:1473-1482) and as allegedly anticipated under 35 U.S.C. § 102(a) by WO 01/07084 as evidenced by Kemp, *et al.*, (*Pathobiology*, 1992, 60:27-32). Claims 23-26 and 28-30 are also rejected under 35 U.S.C. § 102(b) as allegedly anticipated by Schultz, *et al.*, (*Cancer Res.*, 2000, 60:6663-6669) as evidenced by Stone, *et al.*, (*Proc. Am. Assoc. Cancer Res. Ann. Mtg.*, 2002, 43:881).

Amendments to the claims.

In order to more clearly claim the current embodiment, claims 23, 24, 28, and 29 are amended herein to specify that the targeting moieties of the compositions are antibodies (as opposed to ligands or scFv) and that the compositions comprise one or more human cells that are to undergo apoptosis or whose growth is to be inhibited. Support for such changes is replete throughout the application as filed. For example, support relating to the change from "targeting moiety" to antibody can be found, e.g., in paragraph 34 and in the Examples, which utilize antibody constructs. Support for recitation of cells within the compositions can be found, e.g., in the Examples which teach the antibody-avidin constructs with carriers and cells whose growth is to be inhibited or in which apoptosis is to be induced. Support for limitation to human cells is shown, e.g., in the Examples. Support for new claim 31 is found, e.g., in claim 23, paragraph 11, paragraph 13, the Examples, etc.

Additional changes to claims 27 and 28 are to correct grammar and antecedent basis.

Because the changes introduce no new matter, Applicants respectfully request their entry.

35 U.S.C. § 112.

Claims 23-25, 26, and 28-30 are rejected in the current Office Action as allegedly failing to comply with the written description requirement of 35 U.S.C. §112. Applicants herein amend and respectfully traverse to the extent that the rejections are applied to the amended claims.

The Office Action alleges that the current claims, which recite "targeting moiety" or "ligand" encompass a wide a variety of molecules "with different structures and functions" while the specification only discloses antibodies as targeting moieties. The Office Action, thus, alleges that the written description is too broad in regard to the disclosure of the specification. While the Applicants believe the range of targeting moieties is described adequately in the specification, Applicants herein amend claim 23 (and hence its dependents) and claims 24, 28, and 29 to recite an antibody as the targeting moiety. As indicated above, support for such change occurs throughout the application as filed. For example, support can be found in, e.g., Figure 1, paragraph 34 (which lists antibodies and antibody fragments as distinct from scFv and receptor ligands), paragraph 70 *et seq.* (describing antibody and antibody fusion proteins), and the Examples.

Because the wording upon which the rejection was based has been amended to that acknowledged by Examiner Sang to be adequately disclosed within the specification, Applicants respectfully request that the rejection be withdrawn.

35 U.S.C. § 102(b).

Claims 23- 30 are rejected in the current Office Action as allegedly anticipated by Penichet *et al.*, *J. Immunol.*, 1999, 163:4421-4426. Applicants herein amend claim 23 (from

which the other pending claims depend) and traverse to the extent that the rejections are applied to the amended claims.

The Office Action cites to description within Penichet that is alleged to disclose a composition comprising an antibody-avidin construct and a carrier without biotin. *Penichet* at 4423. However, as amended, the instant claims require the presence of one or more human cells that are to undergo apoptosis or that are to be inhibited in proliferation. As can be seen in the cited passage from Penichet, the composition therein does not include such cells.

In order for a reference to anticipate a claim "the reference must teach every element of the claim." M.P.E.P. §2131. Additionally, "the identical invention must be shown as in as complete detail as is contained in the ... claim." *Richardson v. Suzuki Motor Co.*, 868 F.2d 1226, 1236, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989). Furthermore, "every element of the claimed invention must be identically shown in a single reference," and the "elements must be arranged as in the claim under review." *See In re Bond*, 910 F.2d 831, 15 USPQ2d 1566 (Fed. Cir. 1990).

Applicants respectfully submit that Penichet does not present all elements of the amended claims and thus cannot anticipate them. For example, while Penichet may teach antibody-avidin constructs in PBS solution presumably without biotin, the instant claims are drawn to compositions that comprise antibody-avidin constructs, a pharmaceutically acceptable carrier and one or more cells to be inhibited or to undergo apoptosis, which composition does not comprise biotin or a biotinylated molecule. As can be seen, the composition in the cited passage in Penichet, which is a storage composition, clearly does not include one or more cells that are to be inhibited or that are to undergo apoptosis.

Because Penichet does not recite all of the limitations of the claims as amended, Applicants respectfully request that the rejection be withdrawn.

35 U.S.C. § 102(a).

Claims 23- 30 are rejected in the current Office Action as allegedly anticipated under 35 U.S.C. § 102(a) by WO 01/07084 as evidenced by Kemp, *et al.*, *Pathobiology*, 1992,

60:27-32. Applicants herein amend claim 23 (from which the other pending claims depend) and respectfully traverse to the extent that the rejection is applied to the amended claims.

The Office Action points to WO 01/07084 as teaching an antibody-avidin fusion protein that presumably is present in a water or buffer solution without biotin when its protein concentration is determined. The Office Action, thus, alleges that WO 01/07084 anticipates the instant compositions. Here too, however, the reference does not teach all elements of the amended claims.

Applicants respectfully point out that even assuming, *arguendo*, that it does teach an antibody-avidin structure in a carrier without biotin, WO 01/07084 still does not teach a composition comprising an antibody-avidin construct along with a pharmaceutical carrier and one or more human cells which are to be inhibited or to undergo apoptosis, wherein the composition does not comprise biotin or a biotinylated molecule. The passages relied on by the Office Action do not show that the composition comprises cells that are to be inhibited or which are to undergo apoptosis. Instead, the cited lines indicate that the composition was for a protein assay to determine concentration of the antibody construct and, thus, logically would not include such cells.

Thus, since WO 01/07084 does not teach all elements of the amended claims, Applicants respectfully request that the rejection be withdrawn.

35 U.S.C. § 102(b).

Claims 23-26 and 28-30 are rejected in the current Office Action as allegedly anticipated under 35 U.S.C. § 102(b) by Schultz, *et al.*, *Cancer Res.*, 2000, 60:6663-6669 as evidenced by Stone, *et al.*, *Proc. Am. Assoc. Cancer Res. Ann. Mtg.*, 2002, 43:881. Applicants herein amend claim 23, and hence its dependents, and respectfully traverse to the extent that the rejection remains after amendment.

The Office Action alleges that Schultz teaches compositions comprising tetravalent single-chain antibody-streptavidin fusion proteins and a pharmaceutical carrier wherein the composition does not comprise biotin. Schultz at 6663. However, as with the previous references, Schultz does not present all elements of the amended claims and so cannot anticipate the instant claims.

While Schultz may allegedly teach compositions that comprise an scFv-avidin construct in a pharmaceutical carrier without biotin, etc., it does not comprise antibody-avidin constructs as presented herein. The amended claims specifically comprise antibody-avidin constructs and, as detailed in the specification at, e.g., paragraph 34, the antibody and antibody fragments as in the amended claims are distinct from scFv constructs. Paragraph 34 in the specification states that the fusion proteins of the invention can include, "[i]n addition to antibodies and antibody fragments, receptor ligands or single chain Fvs (scFv)" as the targeting moieties. Such wording differentiates antibodies and antibody fragments (as in the amended claims) from receptor ligands and scFv (the construct in Schultz). Thus, Schultz comprises a different construct than those in the instant claims.

Because Schultz does not present all elements of the amended claims, Applicants respectfully request that the rejection be withdrawn.

CONCLUSION

In view of the foregoing, Applicants believe all claims now pending in this application are in condition for allowance. The issuance of a formal Notice of Allowance at an early date is respectfully requested.

If the claims are deemed not to be in condition for allowance after consideration of this Response, please telephone the undersigned at (510) 769-3507.

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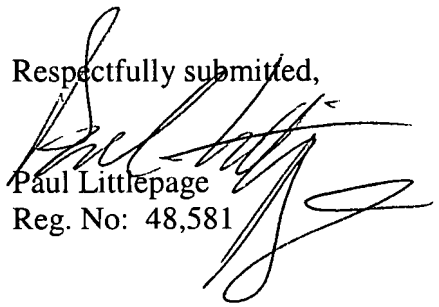
Respectfully submitted,



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